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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,035	02/19/2002	Eliso Quintanilla Almagro	Q64417	3663

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EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/856,035	Almagro et al.
Examiner	**Art Unit**
Christopher Tate	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 23, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above, claim(s) *21-31* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *32-40* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group V, new claims 32-40, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that, at best, the application contains only two inventions - i.e., using *Curcuma longa* extract as a photosensitization agent for treating proliferative diseases; and using *Curcuma* extract as a fibrinogen reducer for treating cardiovascular diseases. This is not found persuasive because, as originally claimed, each of the methods of Groups I-VI was drawn to providing a particular functional effect not shared by the other Groups - as discussed in the previous Office action. Further, new claims 21-31, drawn to a method of treating a proliferative disease, also now requires administration of a *Curcuma* extract in combination with radiation, which is lacking from the elected invention of Group V (new claims 32-40). The requirement is still deemed proper and is therefore made FINAL.

Claims 32-40 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 35, and 37 are rendered vague and indefinite by the phrases "wherein the pharmaceutical composition comprises a *Curcuma* extract" (claim 33), "wherein the pharmaceutical composition is obtainable by extracting *Curcuma* rhizomes using a solubilizing lipophilic compound" (claim 35), and "wherein said pharmaceutical composition further comprises an aqueous extract of *Curcuma*" (claim 37) because in each instance, the metes and bounds of the limitation in independent claim 32: "at least one compound present in *Curcuma* rhizomes" are not clearly nor adequately delineated from these *Curcuma* extract recitations. That is, it is unclear if the pharmaceutical composition is being defined as comprising one or more *Curcuma* compounds plus an additional amount of *Curcuma* extract (aqueous/ethanolic) or if the *Curcuma* (aqueous ethanolic) extracts are defining that the one or more compounds of claim 32 are contained therein (since the instant specification clearly discloses that ethanolic and hydroalcoholic [i.e., aqueous ethanolic] *Curcuma* extract contains the various bioactive curcuminoid compounds responsible for the recited functional effects - such as curcumin and other curcuminoids (see, e.g., pages 9-11 of the instant specification). In addition, the same phrase noted above for claim 35: "the pharmaceutical composition is obtainable by extracting *Curcuma* rhizomes using a solubilizing lipophilic compound" is vague and indefinite because this overall phrase is awkward and confusing with respect to defining the solvent extraction of an herbal plant. For example, this phrase would imply that the overall composition is obtainable via some type of lipophilic compound solubilization and, further, the term "obtainable" is vague and ambiguous (is it or is not actually obtained?). The instant specification appears to disclose

that the one or more *Curcuma* compounds are obtained via alcoholic/hydroalcoholic extraction and, as such, claim 35 should be amended accordingly to clearly define this limitation.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosca et al. (Age, 1997), by Deshpande et al. (Med. Sci. Res., 1997), or by Quiles et al. (BioFactors, 1998), with evidence provided by Tsuda et al. (Atherosclerosis, 1996).

A method of treating a mammal susceptible to a condition associated with fibrinogen disease, such as a cardiovascular disease, via administering to the mammal an effective amount of a pharmaceutical composition comprising one or more compounds present in *Curcuma* rhizomes is claimed. Dependent claims apparently include the compounds being within an aqueous/alcoholic extract of *Curcuma*.

Each of the cited references teach the administration of a pharmaceutical aqueous alcoholic extract of *Curcuma longa* rhizomes (which expressly or admittedly contain one or more inherent curcuminoid compounds therein including curcumin) to humans or to rabbits. Each of the references also expressly teach that the *Curcuma* extracts are useful for treating and/or preventing coronary heart disease such as arteriosclerosis (see entire documents including *Materials and Methods* of each). Please note that since all mammals including humans and rabbits are susceptible to fibrinogen diseases (i.e., no one is immune from these afflictions), the referenced administered humans/rabbits meet the claim limitations with respect to the claimed administered mammal. Further, as evidenced by Tsuda et al., elevated plasma fibrinogen is known to progress atherosclerosis (an extremely common form of arteriosclerosis) and to be one of the risk factors for the occurrence of cardiovascular disease (see, e.g., abstract: please note this reference is only cited as evidence to show the inherent association of elevated plasma fibrinogen levels and arteriosclerosis, and not as prior art). Accordingly, since elevated plasma fibrinogen is an inherent phenomenon associated with arteriosclerosis, the *Curcuma longa* extract-administered arteriosclerotic rabbits taught by Quiles et al. would inherently be treated with respect to the underlying fibrinogen functional effects instantly claimed/disclosed.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 2002/0164374) in view of Bosca et al. (Age, 1997), Deshpande et al. (Med. Sci. Res., 1997), and Quiles et al. (BioFactors, 1998), with evidence provided by Tsuda et al. (Atherosclerosis, 1996).

Jackson et al. teach a pharmaceutical composition (polymeric delivery systems) containing curcumin (obtained from tumeric - i.e., *Curcuma longa*) as an active ingredient therein for treating vascular diseases (e.g., obstructed vessels) such as cardiovascular diseases including atherosclerosis (see, e.g., paragraph [0097] - [0103], [0159], [0229]-[0231], [0236], and claims 20-21). Jackson et al. further teach that, as part of the chain of events leading to the formation of obstructive atherosclerotic vascular plaques and narrowing of the vessels, local concentrations of fibrinogen increase (see, e.g., paragraph [0113]).

The secondary references are relied upon for the reasons discussed *supra*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the curcumin-containing pharmaceutical composition taught by Jackson et al. to a subject suffering from a cardiovascular disease such as atherosclerosis, including atherosclerosis involving vascular plaque formation related to elevated fibrinogen levels (as disclosed by Jackson et al.; and as evidenced by Tsuda et al. - is well known in the art to be an intrinsic phenomenon associated with the progression of atherosclerosis/cardiovascular disease), based upon the beneficial teachings provided by Jackson et al. It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made administer an ethanolic and/or aqueous ethanolic extract of *Curcuma longa* rhizomes to such a subject based upon the beneficial teaching provided by the secondary references with respect to the use of *Curcuma longa* rhizome extracts (which expressly and/or admittedly contain curcumin as well as other curcuminoids therein) for such purpose. Again, please note that since elevated plasma fibrinogen is an inherent phenomenon associated with arteriosclerosis, administration of the reference curcumin and/or *Curcuma* extract cardiovascular-treating compositions would intrinsically provide the underlying fibrinogen functional effects instantly claimed/disclosed.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654